

# Transderm-Nitro<sup>®</sup> nitroglycerin Transdermal Therapeutic System

BRIEF SUMMARY (FOR FULL PRESCRIBING  
INFORMATION, SEE PACKAGE INSERT)

## INDICATIONS AND USAGE

This drug product has been conditionally approved by the FDA for the prevention and treatment of angina pectoris due to coronary artery disease. The conditional approval reflects a determination that the drug may be marketed while further investigation of its effectiveness is undertaken. A final evaluation of the effectiveness of the product will be announced by the FDA.

## CONTRAINDICATIONS

Intolerance of organic nitrate drugs, marked anemia, increased intraocular pressure or increased intracranial pressure.

## WARNINGS

In patients with acute myocardial infarction or congestive heart failure, Transderm-Nitro system should be used under careful clinical and/or hemodynamic monitoring.

In terminating treatment of anginal patients, both the dosage and frequency of application must be gradually reduced over a period of 4 to 6 weeks to prevent sudden withdrawal reactions, which are characteristic of all vasodilators in the nitroglycerin class.

Transdermal nitroglycerin systems should be removed before attempting defibrillation or cardioversion because of the potential for altered electrical conductivity which may enhance the possibility of arcing, a phenomenon associated with the use of defibrillators.

## PRECAUTIONS

Symptoms of hypotension, such as faintness, weakness or dizziness, particularly orthostatic hypotension may be due to overdosage. When these symptoms occur, the dosage should be reduced or use of the product discontinued.

Transderm-Nitro system is not intended for immediate relief of anginal attacks. For this purpose occasional use of the sublingual preparations may be necessary.

## ADVERSE REACTIONS

Transient headaches are the most common side effect, especially when higher doses of the drug are used. These headaches should be treated with mild analgesics while Transderm-Nitro therapy is continued. When such headaches are unresponsive to treatment, the nitroglycerin dosage should be reduced or use of the product discontinued.

Adverse reactions reported less frequently include hypotension, increased heart rate, faintness, flushing, dizziness, nausea and vomiting. These symptoms are attributable to the known pharmacologic effects of nitroglycerin, but may be symptoms of overdosage. When they persist the dose should be reduced or use of the product discontinued. In some patients, dermatitis may occur.

## DOSE AND ADMINISTRATION

Therapy should be initiated with application of one Transderm-Nitro 5 system to the desired area of skin. Many patients prefer the chest; if hair is likely to interfere with system adhesion or removal, it can be clipped prior to placement of the system. Each system is designed to remain in place for 24 hours, and each successive application should be to a different skin area. Transderm-Nitro system should not be applied to the distal parts of the extremities.

The usual dosage is one Transderm-Nitro 5 system every 24 hours. Some patients, however, may require the Transderm-Nitro 10 system. If a single Transderm-Nitro 5 system fails to provide adequate clinical response, the patient should be instructed to remove it and apply either two Transderm-Nitro 5 systems or one Transderm-Nitro 10 system. More systems may be added as indicated by continued careful monitoring of clinical response. The Transderm-Nitro 2.5 system is useful principally for decreasing the dosage gradually, though it may provide adequate therapy for some patients when used alone.

The optimal dosage should be selected based upon the clinical response, side effects, and the effects of therapy upon blood pressure. The greatest attainable decrease in resting blood pressure that is not associated with clinical symptoms of hypotension especially during orthostasis indicates the optimal dosage. To decrease adverse reactions, the size and/or number of systems should be tailored to the individual patient's needs. Do not store above 86°F (30°C).

## PATIENT INSTRUCTIONS FOR APPLICATIONS

A patient leaflet is supplied with the systems.

## HOW SUPPLIED

Transderm-Nitro System Rated Release <i>in vivo</i>	Total Nitroglycerin in System	System Size	Carton Size
2.5 mg/24 hr	12.5 mg	5 cm <sup>2</sup>	30 Systems (NDC 0083-2025-26) *100 Systems (NDC 0083-2025-30)
5 mg/24 hr	25 mg	10 cm <sup>2</sup>	30 Systems (NDC 0083-2105-26) *100 Systems (NDC 0083-2105-30)
10 mg/24 hr	50 mg	20 cm <sup>2</sup>	30 Systems (NDC 0083-2110-26) *100 Systems (NDC 0083-2110-30)
15 mg/24 hr	75 mg	30 cm <sup>2</sup>	30 Systems (NDC 0083-2115-26) *100 Systems (NDC 0083-2115-30)

\*Hospital Pack 100's

C85-35 (Rev. 11/85)

## Dist. by:

CIBA Pharmaceutical Company  
Division of CIBA-GEIGY Corporation  
Summit, New Jersey 07901

All transdermal nitroglycerin products are being marketed pending final evaluation of effectiveness by the FDA.

# In Memoriam

## California Medical Association

AMANO, FUMIKO Y., Los Angeles. Died Jan 8, 1987, aged 83. Graduate of Yale University School of Medicine, New Haven, Connecticut, 1929. Licensed in California in 1930. Dr Amano was a member of the Los Angeles County Medical Association.

ASH, DONALD W., Oakland. Died Apr 7, 1987, aged 74. Graduate of Tufts College Medical School, Boston, 1941. Licensed in California in 1944. Dr Ash was a member of the Alameda-Contra Costa Medical Association.

BERKOVE, SADIE VOLOVICK, Oakland. Died Jan 23, 1987, aged 79. Graduate of University of California, San Francisco, 1931. Licensed in California in 1931. Dr Berkove was a member of the Alameda-Contra Costa Medical Association.

BJORNSON, LYALL A., Oxnard. Died Mar 3, 1987, aged 45. Graduate of Bowman Gray School of Medicine, Winston-Salem, North Carolina, 1966. Licensed in California in 1969. Dr Bjornson was a member of the Ventura County Medical Society.

CALVIN, GEORGE, Walnut Creek. Died Mar 13, 1987, aged 86. Graduate of University of Pennsylvania School of Medicine, Philadelphia, 1926. Licensed in California in 1929. Dr Calvin was a member of the Alameda-Contra Costa Medical Association.

CARLSON, CARL O., San Jose. Died Mar 20, 1987, aged 74. Graduate of Stanford University School of Medicine, 1939. Licensed in California in 1939. Dr Carlson was a member of the Santa Clara County Medical Society.

DICKSON, JAMES D. Died Jan 1987, aged 72. Graduate of Tulane University School of Medicine, New Orleans, 1938. Licensed in California in 1943. Dr Dickson was a member of the Shasta-Trinity County Medical Society.

DODSON, JERRY G., La Habra. Died Feb 15, 1987, aged 58. Graduate of Johns Hopkins University School of Medicine, Baltimore, 1955. Licensed in California in 1963. Dr Dodson was a member of the Orange County Medical Association.

FIELDS, JACK, North Hollywood. Died Feb 2, 1987, aged 76. Graduate of University of Illinois, Chicago, 1937. Licensed in California in 1947. Dr Fields was a member of the Los Angeles County Medical Association.

FUNK, JOHN W., Riverside. Died Mar 13, 1987, aged 72. Graduate of Indiana University School of Medicine, Indianapolis, 1943. Dr Funk was a member of the Riverside County Medical Association.

GAEDE, MENNO S., Reedley. Died Feb 8, 1987, aged 85. Graduate of University of Kansas School of Medicine, Kansas City, 1928. Licensed in California in 1930. Dr Gaede was a member of the Fresno-Madera Medical Society.

GRONHOVD, GILBERT O., Anaheim. Died Mar 15, 1987, aged 88. Graduate of Rush Medical College, Chicago, 1931. Licensed in California in 1932. Dr Gronhovd was a member of the Los Angeles County Medical Association.

HACKLEY, ROGER W., Oakland. Died Apr 3, 1987, aged 74. Graduate of University of California, 1939. Licensed in California in 1939. Dr Hackley was a member of the Alameda-Contra Costa Medical Association.

HARMON, ELLIS D., San Francisco. Died Feb 9, 1987, aged 89. Graduate of University of California, San Francisco, 1929. Licensed in California in 1929. Dr Harmon was a member of the San Francisco Medical Society.

HARVEY, BERNARD J., Pomona. Died Mar 27, 1987, aged 76. Graduate of University of Nebraska College of Medicine, Omaha, 1935. Licensed in California in 1946. Dr Harvey was a member of the Los Angeles County Medical Association.

HICKMAN, KYRMEL L., Fresno. Died Jan 22, 1987, aged 77. Graduate of University of California, Irvine. Dr Hickman was a member of the Fresno-Madera Medical Society.

HINES, PHILLIP ROGER, Vallejo. Died Mar 16, 1987, aged 36. Graduate of Medical College of Ohio at Toledo, 1976. Licensed in California in 1978. Dr Hines was a member of the Solano County Medical Society.

JACKSON, LETA B., Sacramento. Died Nov 27, 1986, aged 84. Graduate of University of California, Irvine. Dr Jackson was a member of the Sacramento-El Dorado Medical Society.

KESTERSON, ROBERT L. Died Mar 26, 1987, aged 71. Graduate of University of Louisville, 1940. Licensed in California in 1941. Dr Kesterson was a member of the Alameda-Contra Costa Medical Association.

LEONARD, NOBLE D., San Francisco. Died Dec 17, 1986, aged 84. Graduate of University of Michigan Medical School, Ann Arbor, 1929. Licensed in California in 1948. Dr Leonard was a member of the San Francisco Medical Society.

LEVIN, SIDNEY, San Francisco. Died Mar 18, 1987, aged 59. Graduate of University of California, San Francisco, 1950. Licensed in California in 1950. Dr Levin was a member of the San Francisco Medical Society.

LOUIE, STANLEY, San Francisco. Died Mar 24, 1987, aged 78. Graduate of Harvard Medical School, Boston, 1937. Licensed in California in 1939. Dr Louie was a member of the San Francisco Medical Society.

LUKENS, JAMES T., Carmichael. Died Mar 12, 1987, aged 62. Graduate of University of Maryland, Baltimore, 1949. Licensed in California in 1956. Dr Lukens was a member of the Sacramento-El Dorado Medical Society.

MAHER, FRANK M., San Jose. Died Feb 25, 1986, aged 70. Graduate of Northwestern University Medical School, Chicago, 1944. Dr Maher was a member of the Santa Clara County Medical Society.

(Continued on Page 796)

## Routine VI-FLOR® supplementation

to help you guard appropriate patients against caries risk and nutritional risk.

**INDICATIONS AND USAGE:** Prophylaxis of vitamin deficiencies and dental caries in children and adults when fluoride of water supply does not exceed 0.7 ppm.<sup>1,2,3</sup> And, in the case of TRI-VI-FLOR® 0.25 mg Drops with Iron and POLY-VI-FLOR® Drops and Chewable Tablets with Iron, prophylaxis against iron deficiencies. Note: VI-FLOR Drops do not contain folic acid because the vitamin is not stable in liquid form.

**PRECAUTIONS:** Do not exceed recommended dose or give concurrently with other medications containing significant amounts of fluoride. Prolonged excessive fluoride intake may cause dental fluorosis. All VI-FLOR® with Iron products: as with all products containing iron, parents should be warned against excessive dosage. The bottle should be kept out of reach of children.

Keep all VI-FLOR with Iron products tightly closed and away from direct light.

VI-FLOR Drops should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation.

**ADVERSE REACTIONS:** Allergic rash has rarely been reported.

**DOSE AND ADMINISTRATION:**  
Supplemental Fluoride Dosage Schedule (mg/day)\*

Age	Concentration of Fluoride in Drinking Water (ppm)		
	<0.3	0.3-0.7	>0.7
2-wk-2 yr**	0.25	0	0
2-3 yr	0.5	0.25	0
3-16 yr	1.0	0.5	0

\*From the American Academy of Pediatrics Committee on Nutrition statement. Fluoride Supplementation: Revised Dosage Schedule. *Pediatrics* 63(1):150-152, 1979.

\*\*The Committee favors initiating fluoride supplementation shortly after birth in breast-fed infants (0.25 mg F/day). In formula-fed infants, fluoride supplementation should be according to the fluoride content of the water used to prepare formula.

PRODUCT	FORM	SIZE	FLUORIDE mg/dose
POLY-VI-FLOR	Drops	50 ml Bottle	0.25
0.25 mg			
POLY-VI-FLOR	Drops	50 ml Bottle	0.25
0.25 mg with Iron			
POLY-VI-FLOR	Tablets	Bottle of 100	0.25
0.25 mg			
POLY-VI-FLOR	Tablets	Bottle of 100	0.25
0.25 mg with Iron			
POLY-VI-FLOR	Drops	50 ml Bottle	0.5
0.5 mg			
POLY-VI-FLOR	Drops	50 ml Bottle	0.5
0.5 mg with Iron			
POLY-VI-FLOR	Tablets	Bottle of 100	0.5
0.5 mg			
POLY-VI-FLOR	Tablets	Bottle of 100	0.5
0.5 mg with Iron			
POLY-VI-FLOR	Tablets	Bottle of 100	1.0
1.0 mg			
POLY-VI-FLOR	Tablets	Bottle of 100	1.0
1.0 mg with Iron			
TRI-VI-FLOR	Drops	50 ml Bottle	0.25
0.25 mg			
TRI-VI-FLOR	Drops	50 ml Bottle	0.25
0.25 mg with Iron			
TRI-VI-FLOR	Drops	50 ml Bottle	0.5
0.5 mg			
TRI-VI-FLOR	Tablets	Bottle of 100	1.0
1.0 mg			

### REFERENCES:

- Hennon DK, Stookey GK and Muhler JC: The Clinical Anticariogenic Effectiveness of Supplementary Fluoride-Vitamin Preparations—Results at the End of Four Years. *J Dentistry for Children* 34:439-443 (Nov) 1967.
- Hennon DK, Stookey GK and Muhler JC: The Clinical Anticariogenic Effectiveness of Supplementary Fluoride-Vitamin Preparations—Results at the End of Five and a Half Years. *Pharmacology and Therapeutics in Dentistry* 1:1-6 (Oct) 1970.
- Hennon DK, Stookey GK and Muhler JC: Prophylaxis of Dental Caries: Relative Effectiveness of Chewable Fluoride Preparations With and Without Added Vitamins. *J Pediatrics* 80:1018-1021 (June) 1972.

VI-SOL®/VI-FLOR® products are the nation's most prescribed children's vitamin and vitamin-fluoride supplements.

(For complete details, please consult full prescribing information.)

**Mead Johnson**  
NUTRITIONAL DIVISION

## In Memoriam

(Continued from Page 780)

MARTEL, JULIUS, San Pablo. Died Mar 13, 1987, aged 57. Graduate of University of California, Irvine. Dr Martel was a member of the Alameda-Contra Costa Medical Association.

MILLS, WILLIAM, Oakland. Died Mar 9, 1987, aged 91. Graduate of University of Pennsylvania School of Medicine, Philadelphia, 1920. Licensed in California in 1921. Dr Mills was a member of the Alameda-Contra Costa Medical Association.

MITCHELL, ALLEN C. Died Mar 7, 1987, aged 72. Graduate of Stanford University School of Medicine, 1940. Licensed in California in 1940. Dr Mitchell was a member of the Monterey County Medical Society.

O'NEIL, ALBERT A. Died Jan 21, 1987, aged 69 years. Graduate of University of Manitoba Faculty of Medicine, Winnipeg, 1943. Licensed in California in 1949. Dr O'Neil was a member of the Alameda-Contra Costa Medical Association.

PILSON, MORRIS J. Died Feb 8, 1987, aged 91. Graduate of Los Angeles College of Osteopathy, 1933. Licensed in California in 1933. Dr Pilson was a member of the Los Angeles County Medical Association.

RICHARDS, GEORGE M., Santa Barbara. Died Feb 21, 1987, aged 95. Graduate of Albany Medical College, Albany, New York, 1916. Licensed in California in 1951. Dr Richards was a member of the Santa Barbara County Medical Society.

ROBBINS, EDWARD D., San Francisco. Died Mar 24, 1987, aged 69. Graduate of University of Chicago, 1943. Licensed in California in 1950. Dr Robbins was a member of the San Francisco Medical Society.

ROBERTSON, EVALYN, Oakland. Died Jan 24, 1987, aged 56. Graduate of University of Cincinnati College of Medicine, 1960. Licensed in California in 1960. Dr Robertson was a member of the Alameda-Contra Costa Medical Association.

SHEPPARD, WILLIAM B. Died Mar 28, 1987, aged 78. Graduate of Johns Hopkins University School of Medicine, 1935. Licensed in California in 1948. Dr Sheppard was a member of the Alameda-Contra Costa Medical Association.

THORPE, H. HARPER. Died Jan 19, 1987, aged 70. Graduate of Northwestern University Medical School, Chicago, 1943. Licensed in California in 1946. Dr Thorpe was a member of the Shasta-Trinity County Medical Society.

WILSON, RODNEY GUY. Died Mar 7, 1987, aged 73. Graduate of University of California, Irvine. Dr Wilson was a member of the Los Angeles County Medical Association.

### New Mexico Medical Society

BIRCH, JOHN H., Albuquerque. Died Jan 16, 1987, aged 60. Graduate of the Medical School University of Birmingham, England, 1948. Licensed in New Mexico in 1960. Dr Birch was a member of the greater Albuquerque Medical Association.

MOSELEY, ROBERT D., Albuquerque. Died Mar 12, 1987, aged 63. Graduate of Louisiana State University, New Orleans, 1947. Licensed in New Mexico in 1950. Dr Moseley was a member of the Greater Albuquerque Medical Association.

OAKES, WILLIAM R., Los Alamos. Died Feb 1, 1987, aged 82. Graduate of Yale University School of Medicine, New Haven, Connecticut, 1940. Licensed in New Mexico in 1947. Dr Oakes was a member of the Los Alamos County Medical Society.

TIEDEMANN, JOHN H., Belen. Died Apr 13, 1987, aged 82. Graduate of Middlesex University School of Medicine, Waltham, Mass, 1943. Licensed in New Mexico in 1965. Dr Tiedemann was a member of the Mid-Rio Grande County Medical Society.

### Utah State Medical Association

ELY, ROBERT S., Salt Lake City. Died Mar 5, 1987, aged 65. Graduate of University of Minnesota. Licensed in Utah in 1951. Dr Ely was a member of the Salt Lake County Medical Society.

NORTON, MINTHORNE D., Price. Died Mar 19, 1987, aged 49. Graduate of University of Miami. Dr Norton was a member of the Carbon County Medical Society.

# WHY AMA?

The AMA can help you build and improve the efficiency of your practice through Practice Management seminars and audio visual courses. These programs are designed to assist you in every phase of your practice by providing you with practical information about business procedures and management techniques. Practice Management: it's one more good reason why you should be a part of the AMA.

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